60th Medical Group (AMC), Travis AFB, CA

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

FINAL REPORT SUMMARY

(Please type all information. Use additional pages if necessary.)

PROTOCOL #: FDG20150031A **DATE:** 24 July 2016

PROTOCOL TITLE: Technique Refinement and Validation of Variable Aortic Occlusion via Extracorporeal Flow Circuit in a Pig model (*Sus scrofa*) of Uncontrolled Hemorrhage with Subsequent Resuscitation and Critical Care.

PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC): Lt Col Timothy Williams

DEPARTMENT: HLVC **PHONE #:** 423-2300

INITIAL APPROVAL DATE: 5 August 2015 **LAST TRIENNIAL REVISION DATE:** N/A

FUNDING SOURCE: HQ USAF SG

1. **RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
Sus scrofa	**30**	**0**	**14**

2. **PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

___ Training: Live Animal	___ Medical Readiness	___ Prolonged Restraint
___ Training: non-Live Animal	___ Health Promotion	___ Multiple Survival Surgery
___ Research: Survival (chronic)	___ Prevention	___ Behavioral Study
__x_ Research: non-Survival (acute)	___ Utilization Mgt.	___ Adjuvant Use
___ Other ( )	__x_ Other (Treatment)	___ Biohazard

3. **PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ___ C _X_ D ___ E

4. **PROTOCOL STATUS:**

***Request Protocol Closure:**

___ Inactive, protocol never initiated

___ Inactive, protocol initiated but has not/will not be completed

__x_ Completed, all approved procedures/animal uses have been completed

5. **Previous Amendments:**
List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

For the Entire Study Chronologically

Amendment Number	Date of Approval	Summary of the Change
1	26 June 2016	Personnel

6. **FUNDING STATUS:** Funding allocated: $16,800.00 Funds remaining: $0.00

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review? __x_ Yes ___ No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC *has* approved this addition.

ADDITIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

_____

_____

DELETIONS: (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

Maj Lucas Neff, Co-PI, 26 Jun 2016 (Amendment 1).

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

No problems identified regarding the conduct of the protocol.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

REPLACEMENT (ALTERNATIVES): Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No.

REFINEMENT: Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No refinements have been required or indicated based on the conduct of the experiments conducted thus far.

REDUCTION: Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

The study was completed utilizing 14 of the 30 available animals on the protocol.

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

Williams TK, Neff LP, Johnson MA, Russo RM, Ferencz S-A, Davidson AJ, Rasmussen TE. Extending REBOA: Endovascular Variable Aortic Control (EVAC) in a Lethal Model of Hemorrhagic Shock. The Journal of Trauma and Acute Care Surgery. 2016.

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Protocol objectives were met. The study yielded valuable data regarding a next generation resuscitation paradigm for hemorrhagic shock.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

(PI / TC Signature)

24 Aug 16

(Date)

Attachments:
Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

Attachment 1
Defense Technical Information Center (DTIC) Abstract Submission

This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.

Objectives: The purpose of the study was to develop and refine the technique of permissive regional hypoperfusion in a large animal model to serve as a foundation for further investigation. This novel therapy is targeted towards non-compressible truncal hemorrhage, a major source of death on the battlefield.

Methods: The study utilized a novel extracorporeal flow circuit capable of delivering tightly regulated distal aortic blood flow. Animals underwent a uniformly lethal liver injury, were then subjected to a brief period of complete aortic occlusion followed by a prolonged period of distal regional hypoperfusion. Subsequently, the liver injury was controlled and the animals were resuscitated with blood during a critical care phase.

Results: This resuscitation strategy prevented early demise of the study animals and minimized the ischemic insult to distal vascular beds, thus preserving organ viability as evidenced by early return of urine output and clearing of lactate levels in most animals.

Conclusion: This study serves as foundational evidence for the viability of this resuscitative paradigm. In otherwise fatal injuries, these animals survived with near normal physiologic parameters at the end of the study period. Further studies have been conducted under other IACUC approved protocols, confirming efficacy of this strategy.

Grant Number:_____
From:_____
****If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**